Docket No. 20784/6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Hans-Ulrich Demuth et al. ART UNIT: 1646

SERIAL NO.: 10/082,001

FILED: February 22, 2002

FOR: ***NEW EFFECTORS OF DIPEPTIDYL PEPTIDASE IV FOR TOPICAL USE***

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, Washington, D.C., 20231-0001

By: Sandra Graves October 28, 2002
Sandra J. Graves Date

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Date: October 28, 2002

Pursuant to Applicant(s) duty of disclosure, the information listed in the attached form PTO-1449 is brought to the attention of the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

In accordance with the requirement under 37 C.F.R. 1.98 (3)(i), the following are concise explanations of the relevance, as presently understood, with regard to those items submitted herewith that are not in the English language:

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

a. ☐ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).

b. ☒ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

FRENCH LANGUAGE FR 2 696 740 Applicants have relied on an English language abstract in determining that this patent apparently relates to Dimethylbiguanide drug derivatives and their medical applications.

FRENCH LANGUAGE FR 2 085 665 Applicants have relied on an English language abstract in determining that this patent apparently relates to biguanide substitutes possessing a hypoglycemic property.

GERMAN LANGUAGE DT 25 42 598 A1 Applicants have relied on an English language abstract in determining that this patent apparently relates to biguanide salts as well as a method for preparing such salts. In addition to this the invention apparently covers pharmaceutical compounds which contain such salts.

GERMAN LANGUAGE WO 97/40832 Applicants have relied on an English language abstract in determining that this patent apparently relates

to the use of a method for reducing in the blood of a mammal by administration of effectors the enzyme activity of dipeptidyl peptidase (DP IV) or enzyme activity similar to DP IV, the endogenous (or additionally exogenously administered) insulinotropic peptide gastric inhibitory polypeptide 1-42 and glucagon-like peptide amide-1 7-36 are decomposed in a causal sequence to a reduced extent by DP IV enzymes or those similar to DP IV.

JAPANESE PATENT JP 4-334357A2: Applicants have relied on an English language abstract in determining that this patent ACYL DERIVATIVE HAVING ENZYME-INHIBITING ACTION, apparently relates to a compound having a prolyl endopeptibase activity-inhibiting action and useful as an antidement agent, especially an anti-amnestic agent.

GERMAN LANGUAGE DE 299 09 210 U1 Applicants have relied on an English language abstract in determining that this patent apparently relates to dipeptide compounds or compounds analogous to dipeptide compounds, which are made of an amino acid and a thiazolidine or pyrrolidine group, and to their salts. The invention further relates to the use of these compounds in the treatment of impaired glucose tolerance, glucosuria, hyperlipidemia, metabolic acidosis, diabetes mellitus, diabetic neuropathy and nephropathy as well as secondary diseases of diabetes mellitus in mammals.

c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)
(check one box)

a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.

b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.

c. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e)below,

or, if no certification has been made, charge our deposit account a fee in the amount of $180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

a. ☐ No certification; therefore, a fee in the amount of $180.00 is required by 37 C.F.R. § 1.17(p).

or

b. ☐ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby certifies that

a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office as indicated in the Form 1449 by those references having an asterisk(*). As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

☐ A check in the amount of $180.00 is enclosed for the above-indicated fee. A duplicate copy of this paper is attached.

☒ No fee is required.

VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.704(d) (PATENT TERM ADJUSTMENT)

Applies to original applications (other than design) filed on or after May 29, 2000.

a. _____ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56© more than thirty days prior to the filing of the Information Disclosure Statement.

b. __X__ Enclosed herewith is form PTO-1449.

c. __X__ Copies of cited references are enclosed.

d. _____ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

If the Examiner has any questions concerning this IDS, the Examiner is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge any additional fees to Deposit Account No. 50-0369.

Respectfully submitted,

Date: October 28, 2002

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 20784/6	SERIAL NO. 10/082,001
	APPLICANT(S): **Demuth et al.**	
	FILING DATE: **February 22, 2002**	ART UNIT: **1646**

UNITED STATES PATENT DOCUMENTS

EXAM. INITIAL		DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
	AA	2,961,377	11/22/1960	Shapiro et al.	167	65	
	AB	3,174,901	03/23/1965	Sterne	167	65	
	AC	3,879,541	04/22/1975	Kabbe et al.	424	326	
	AD	3,960,949	06/01/1976	Ahrens et al.	260	564 B	
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	AG	5,433,955	07/18/1995	Bredehorst et al.	424	94.3	
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	BA	WO 01/62266 A2	08/30/2001	PCT	A61K	38/00	Y
	BB	WO 00/53171	09/14/2000	PCT	A61K	31/155	Y
	BC	DT 25 42 598 A1	04/22/1976	Germany	C07C	129/16	N
	BD	FR 2 696 740 A1	04/15/1994	France	C07D	207/404	N
	BE	FR 2 085 665	12/31/1971	France	A61K	27/00	N
	BF	WO 97/40832	11/06/1997	PCT	A61K	31/425	Abstract only

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N
	BG	WO 95/15309	06/08/1995	PCT	C07D	207/16	Y
	BH	JP 4334357	11/20/1992	Japan	C07C	233/57	Abstract only
	BI	WO 93/08259	04/29/1993	PCT	C12N		Y
	BJ	WO 95/11689	05/04/1995	PCT	A61K	37/00	Y
	BK	WO 97/45117	12/04/1997	PCT	A61K	31/435	Y
	BL	DE 196 16 486 C2	10/30/1997	Germany	A61K	45/00	Y
	BM	WO 95/29691	11/09/1995	PCT	A61K	38/00	Y
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	BW	WO 98/19998	05/14/1998	PCT	C07D	207/00	Y
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	BAA	DE 299 09 210 U	09/09/1999	Germany	A61K	31/425	N

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OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

	CA	Campbell, I.W. New Antidiabetic Drugs, ed. C.J. Bailey & P.R. Flatt, Smith-Gordon, "Sulphonylureas and metformin: efficacy and inadequacy". 3:33-51 (1990).
	CB	The Merck Index, 11th Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1989, Page 934
	CC	The Merck Index, 12th Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1996, Page 1014.
	CD	Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 1619.
	CE	Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 36.
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	CG	CHEMICAL ABSTRACTS, vol. 126, no. 2, 13. January 1997 (1997-01-13) Columbus, Ohio, US; abstract no. 16161j, STOECKEL A. ET AL: "Competitive inhibition of proline specific enzymes by amino acid thioxopyrrolidides and thiazolidides".
	CH	CHEMICAL ABSTRACTS, vol. 118, no. 25, 21. June 1993 (1993-06-21) Columbus, Ohio, US; abstract no. 255342k, Hosoda, et al, "Preparation of N-(heterocyclic Carbonyl) Amino Acids and Analogs as Prolyl Endopeptidase Inhibitors", November 1992 (1992-11-20)
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	CL	TANKA, S., et al., "Suppression of arthritis by the inhibitors of dipeptidyl peptidase IV". Int. J. Immunopharmacol, Vol. 19, No. 1 Pages 15-24, (1997)
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	CQ	GOSSRAU, R.; "Cytochemistry of Membrane Proteases". Histochem J, 1985, July; 17 (7) :737-71, 1 page.
	CR	HAHN, T.; et al.; "Enzyme Histochemical Evidence for the Presence of Potential Blood Pressure Regulating Proteases in Cultured Villous Explants from Human First Trimester Placentae". Acta Histochem 1993, December, 95 (2) :185-92, 1 page.
	CS	HEYMANN, E. et al., "Has Dipeptidyl Peptidase IV an Effect on Blood Pressure and Coagulation." Klin Wochenschr, 1984, January, 2;62 (1) :2-10, 1 page.
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	CV	QURESHI. N.U.; et al., "Endogenous Neuropeptide Y Mediates Vasoconstriction during Endotoxic and Hemorrhagic Shock". Regul Pept, 1998, September 25; 75-76:215-20, 1 page.
	CW	Index Nominum, International Drug Directory 1992/1993, Medpharm Scientific Publishers, pages 728-729.
	CX	The Merck Index, An Encyclopedia of Chemicals and Drugs, 9th Edition, Merck & Co., Inc., 1976, page 773
	CY	Willms et al., Journal of Clinical Endocrinology Metabolism, "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients", 1996, 81(1): 327-332.
	CZ	Hoffmann et al., Journal of Chromatography A, "Inhibition of dipeptidyl peptidase IV (DP IV) by anti-DP IV antibodies and non-substrate X-X-Pro- oligopeptides ascertained by capillary eletrophoresis", 1995, 716:355-362.
	CAA	C.B. Welch, Medical Management of Non-Insulin-Dependent (Type II) Diabetes, 3rd edition, American Diabetes Association, "Diagnosis and Classification" p. 3, 1994, Pharmacologic Intervention (2 pages).
	CAB	Mannucci et al., Diabetes Care, "Effect of Metformin on Glucagon-Like Peptide 1 (GLP-1) and Leptin Levels in Obese Nondiabetic Subjects", 24(3): 489-494, March 2001.
	CAC	Stryer, Biochemistry 3rd Ed., "Protein Conformation, Dynamics, and Function", 1988, p 191-193.
	CAD	Pauly et al., Regulatory Peptides, "Abstracts Issue: Abstracts from the 11th International Symposium on Regulatory Peptides", July 15, 1996, 64(1-3): 148 plus cover.
	CAE	Gutniak et al., New England Journal of Medicine, "Antidiabetogenic Effect of Glucagon-like peptide-1 (7-36) Amide in Normal Subjects and Patients With Diabetes Mellitus", 1992, 326: 1316-1322.
	CAF	Hendrick et al., Metabolism – Clinical and Experimental, "Glucagon-like Peptide-I-(7-37) Suppresses Hyperglycemia in Rats", January 1993, 42(1): 1-6.

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	CAG	Nauck et al., Diabetologia, "Normalization of fasting hyperglycaemia by exogenous glucagon-like peptide 1 (7-36 amide) in Type 2 (non-insulin-dependent) diabetic patients", (1993), 36: 741-744.
	CAH	Gutniak et al., Diabetes Care, "Subcutaneous Injection of the Incretin Hormone Glucagon-Like Peptide 1 Abolishes Postprandial Glycemia in NIDDM", September 1994, 17(9): 1039-1044.
	CAI	Deacon et al., Journal of Clinical Endocrinology and Metabolism, "Degradation of Glucagon-Like Peptide-1 by Human Plasma in Vitro Yields and N-Terminally Truncated Peptide That Is a Major Endogenous Metabolite in Vivo", (1995), 80(3): 952-957.
	CAJ	H.A. Smith et al., Veterinary Pathology (fourth edition), "Diseases and Disorders of Metabolism: Deficiency Diseases", (1972), p 1018-1020.
	CAK	G.G. Duncan, Diseases of Metabolism (Asian edition), "Diabetes Mellitus", (1966), p 951-957.
	CAL	T.J. Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypetide and Truncated Glucagon-Like Peptide 1 In Vitro and In Vivo by DP IV", Endocrinology, Vol. 136(8), (1995), p 3585-3596.
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	CAN	Pauly et al., Metabolism, "Improved Glucose Tolerance in Rats Treated with the Dipeptidyl Peptidase IV (CD26) Inhibitor Ile-Thiazolidide", (1999), 48(3): 385-389.
	CAO	Vidal, (1993), 69th Edition, p. 612-613.
	CAP	Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, (1996), p. 1510.
	CAQ	Nathan et al., Diabetes Care, "Insulinotropic Action of Glucagonlike Peptide-1-(7-37) in Diabetic and Nondiabetic Subjects", February 1992, 15(2): 270-275.
	CAR	Pschyrembel, Kininisches Wörterbuch 257, Auflage, (1994), 9 pages.
	CAS	Frohman et al., Journal of Clin. Invest., "Rapid Enzymatic Degradation of Growth Hormone-releasing Hormone by Plasma in Vitro and in Vivo to a Biologically Inactive Product Cleaved at the NH_2 Terminus", Volume 78, October 1986, p 906-913
	CAT	Snow et al., Advances In Medicinal Chemistry, "Boronic Acid Inhibitors of Dipeptidyl Peptidase IV: A New Class of Immunosuppressive Agents", Vol. 3, (1995), p 149-177.
	CAU	Thorens et al., Diabetes, "Glucagon-Like Pepetide-I and the Control of Insulin Secretion in the Normal State and in NIDDM", (1993), 42:1219-1225.
	CAV	Wakselman et al., "Inhibition of HIV-1 infection of CD 26^+ but not CD 26^- cells by a potent cyclopeptidic inhibitor of the DPP IV activity of CD26", Abstract P 44 of the 24th European Peptide Symposium, (1996).
	CAW	Ashworth et al., BIOORG. MED. CHEM. LETT., "2-Cyanopyrrolidides as Potent, Stable Inhibitors of Dipeptidyl Peptidase IV", (1996), 6(10): 1163-1166.

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	CAX	Endroczi et al., ACTA PHYSIOL. HUNG., "Dipeptidyl peptidase IV (DP IV) and Superoxide Dismutase Activity in Thymus-Derived Lymphocytes: Effects of Inhibitory Pepdides and Zn^{2+} in Vitro", (1990), 75(1): 35-44.
	CAY	Lee, H.S. et al., "Cathepsin B Inhibitory Peptides Derived from β-Casein," Peptides 21 (2000) 807-809.
	CAZ	Edwards, J.V. et al., J. Peptide Res., "Synthesis and Activity of NH_2 - and COOH-Terminal Elastase Recognition Sequences on Cotton," (1999), 54: 536-543.
	CBA	Wettstein, J.G. et al. Pharmacology & Therapeutics, "Central Nervous System Pharmacology of Neuropeptide Y.", (1995), 65(3): 397-414.
	CBB	Badia-Elder N.E. et al., Alcoholism Clinical and Experimental Research, "Effects of Neuropeptide Y (NPY) on Ethanol Intake and Anxiety in High and Low Alcohol Drinking (HAD1/LAD1) Rats", (2000), 24(5): 82A.
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